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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,928	06/29/2006	David James Squirrell	41577326422	9314

23370 7590 02/25/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
02/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,928	SQUIRRELL ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 25-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 25-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

FINAL REJECTION

1. This action is in response to papers filed on November 25, 2009. Applicant's claim amendments requiring additional limitations necessitated new grounds of rejections presented in this Office action. Accordingly, ***THIS ACTION IS MADE FINAL***.

Claim Status

2. Claims 1-17 and 25-47 are pending in this application. Claims 1, 25, 36 and 40 have been amended. Claims 18-24 are cancelled. Claim amendments have been reviewed and entered. Previous rejections under 35 USC 102 and 103(a) not reiterated below have been withdrawn in view of claim amendments. Applicant's arguments filed November 25, 2009 have been fully considered and addressed following rejections.

3. Claims 1-17 and 25-47 are under examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-5, 15, 17, 25, 30, 31 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiramatsu et al (EP 1219965 published May 29, 2001, cited in the IDS filed Feb. 18, 2010).

Claim 1 recites following structural components: (i) a movable platform comprising first and second chambers and a first functional component and (ii) an arm for raising and lowering the functional component. Hiramatsu et al teaches structural components (i) and (ii) as discussed below.

Regarding structural component (i), Hiramatsu et al teaches an apparatus comprising a cartridge container, i.e., platform (Fig. 1, paragraph 0033) comprising: (a) a first chamber 27 suitable for receiving a sample, (b) a second chamber 21 into which an analyte extracted from the sample or a reagent may be delivered (Fig. 1, paragraph 0033) and (c) a nozzle, i.e., a first functional component is on the platform and is releasably stored on the platform and is able to act as a collector for moving the sample, analyte or reagent from container to another container on the turntable (Fig. 1 and paragraph 0044).

Regarding structural component (ii), Hiramatsu et al teaches nozzle driving unit 10, i.e., an arm capable of being raised and lowered and removeably attached to the nozzle, i.e., a first functional component and further teaches that nozzle may be raised and lowered with the arm (Fig. 1, column 5, lines 53-67). Hiramatsu et al further teaches that the operator is responsible for the movement of the platform in alignment with the arm (Fig. 5, paragraphs 0052-0054, 0068 and 0069), which encompasses platform is movable such that any chamber or functional component may be aligned with respect to the nozzle driving unit 10, i.e., an arm.

Regarding claim 3, Hiramatsu et al teaches that the nozzle, i.e., first functional component is attached and detached from the nozzle driving unit 10, i.e., an arm

(paragraphs 0043-0048), which is reasonable interpreted as the arm mechanically removeably attaches to the functional component.

Regarding claim 4, Hiramatsu et al teaches that an arm can be raised or lowered in a substantial vertical direction (paragraph 0047).

Regarding claim 5, Hiramatsu et al teaches that the nozzle (i.e., first functional component) is used to remove reagent from the container (paragraph 0048).

Regarding claim 15, Hiramatsu et al teaches that the chamber of the apparatus comprises predetermined reagents (paragraph 0020).

Regarding claim 17, Hiramatsu et al teaches introducing the sample into the container 28 in the apparatus and mixing the sample (Fig. 1 and paragraphs 0032 and 0033).

Claim 25 recites following structural components: (i) a moveable platform, (ii) a chamber, (iii) a first functional component, (iv) a sealed chamber comprising pre-dispensed reagent and (v) an arm. Hiramatsu et al teaches structural components (i) to (v).

Teachings of Hiramatsu et al regarding structural components (i) to (iii) and (v) are described above. Regarding structural component (iv), Hiramatsu et al teaches a sealed chamber comprising a predispensed reagent for mixing, stirring and diluting fluid sample (i.e., urine or blood) and is arranged on the platform (paragraphs 0020 and 0032), which encompasses processing fluid sample prior to nucleic acid amplification.

Regarding claim 30, Hiramatsu et al teaches that the nozzle, i.e., first functional component is attached and detached from the nozzle driving unit 10, i.e., an arm

(paragraphs 0043-0048), which is reasonable interpreted as the arm mechanically removeably attaches to the functional component.

Regarding claim 31, Hiramatsu et al teaches that the nozzle (i.e., first functional component) is used to remove reagent from the container (paragraph 0048).

Regarding claim 35, Hiramatsu et al teaches introducing the sample into the container 28 in the apparatus and mixing the sample (Fig. 1 and paragraphs 0032 and 0033).

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-6, 8-9 and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koike et al (USPN 5,305,650 issued Apr. 6, 1994).

Regarding claim 1, Koike et al teaches structural components (i) and (ii) as discussed below.

Regarding structural component (i), Koike et al teaches an apparatus comprising a turntable 15, i.e., a moveable platform (Fig. 2, column 4, and line 35) and further teaches that the turn table comprises a sample container 18, i.e., first chamber suitable for receiving a sample (Fig. 2, column 4, lines 45-49). Koike et al also teaches a container 19 (i.e., a second chamber) into which an analyte extracted from the sample or a reagent may be delivered (Fig. 2, lines 49-52). Koike et al further teaches a probe needle 26, i.e., a first functional component (Fig. 1, column 5, lines 53-57), which is releasably stored in place on the apparatus 10 comprising the turntable 15 and able to act as collector for moving the sample from container to another container on the turntable (Fig. 1, column 4, lines 29-37 and column 5, lines 29-51). Koike et al do not teach explicitly that the first functional component is releasably stored from the sample.

Regarding structural component (ii), Koike et al teaches an arm 33 capable of being raised and lowered and removeably attached to the probe needle, i.e., a first functional component and further teaches that probe needle may be raised and lowered with the arm (Fig. 1, column 5, lines 53-67). Koike et al also teaches that the turntable is fixed on a rotating shaft 20 rotated by motor 22 and microcomputer for controlling the desired treatments (Fig. 3, column 2, lines 47-51 and column 5, lines 1-4), which is

configured to align any chamber or probe needle (i.e., functional component) with respect to the arm.

Regarding claim 2, Koike teaches that the turntable, i.e., platform is circular (Fig. 1).

Regarding claim 3, Koike et al teaches that the probe needle 26 is attached and detached from the arm 33 (column 2, lines 28-31), which is reasonable interpreted as the arm mechanically removeably attaches to the functional component.

Regarding claim 4, Koike et al teaches that an arm can be raised or lowered in a substantial vertical direction (column 5, lines 53-67).

Regarding claim 5, Koike et al teaches that the probe needle (i.e., first functional component) is used to remove sample from the container (column 5, lines 29-52).

Regarding claim 6, Koike et al teaches that the containers, i.e., chambers comprise magnetic particles for mixing the sample (column 8, lines 20-23).

Regarding claims 8 and 9, Koike et al teaches the apparatus further comprises a magnet (column 8, lines 17-20).

Regarding claims 11-12, Koike et al teaches that the apparatus comprises a heating block capable of heating the contents of the chamber of the apparatus (column 3, lines 1-4).

Regarding claim 13, Koike et al teaches an ultrasonic oscillator, i.e., physical processor, capable of sonicating the contents of the container of the apparatus (column 8, lines 23-26).

As described above, Koike et al do not teach explicitly that the first functional

component is releasably stored from the sample.

The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Kelly et al explicitly do not teach probe needle, i.e., a first functional component is releasably stored from the sample. However, as described above, Koike et al teaches storing the probe needle on the apparatus 10 comprising turn table 15 containing a plurality of storage regions of different dimensions 16a, 17a and 18a arranged in multiple circular rows for holding containers (Fig. 1 and column 4, lines 24-67 and column 5, lines 38-44). The probe needles of Koike et al even with different diameters (column 5, lines 38-44) may be stored on the platform because they fit on the turntable15 comprising storage region with different dimensions (Fig. 1).

Alternatively, it would have been obvious to one of ordinary skill in the art to provide probe needle, i.e., first functional component on the platform for increasing the fluid delivery efficiency.

The burden is on Applicant to show that the first functional component storage is non-obvious over that of Koike et al.

9. Claims 1, 5-7, 8, 10, 15-17, 25-27, 30-38 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al (USPN 5,305,650 issued Apr. 6, 1994) in view of Jang (USPGPUB 20030082565 filed Fe. 14, 2002).

Claim 10 is dependent from claim 8, which is dependent from 6, which is dependent from 5, which is dependent from 1. Teachings of Koike et al regarding claims 1, 5, 6 and 8 are described above in section 8.

Regarding claim 7, Koike et al do not teach the solid phase binding material is silica.

Regarding claim 10, Koike et al teaches magnetic particles and magnet (column 8, lines 17-24). Magnetic particles of Koike et al solid phase material as defined in the instant claims 8 and 9. Koike et al do not teach first functional component is a sheath which provides an interface between the attracting material and the complex.

Regarding claims 15-17, Koike et al teaches that the predetermined amount of liquid is injected into the container (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach chamber comprising pre-dispensed reagent bound to the solid phase binding material.

Regarding claim 25, Koike et al teaches structural components (i) to (v) except for the pre-dispensed reagent. Jang teaches chambers comprising pre-dispensed reagent as discussed below.

Teachings of Koike et al regarding structural components (i) to (iii) and (v) are described above in section 8.

Regarding structural component 'iv', Koike et al teaches a sealed chamber (column 7, line 8) and further teaches that the predetermined amount of liquid is injected into the container on the turntable (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach a sealed chamber comprising pre-dispensed reagent.

Regarding claim 26, Koike teaches that the turntable, i.e., platform is circular (Fig. 1).

Regarding claim 27, Koike et al teaches chambers from the reagent stations 66

and 67 are moved to turntable and back to reagent station a sealing mechanism for defining a sealing chamber (Figs. 2 and 13B # S29, column 7, lines 15-20 and column 8, lines 53-58), thus teaching an exchangeable chamber. Koike et al do not teach an exchangeable chamber comprising pre-dispensed reagent.

Regarding claim 30, Koike et al teaches that the probe needle 26 is attached and detached from the arm 33 (column 2, lines 28-31), which is reasonable interpreted as the arm mechanically removeably attaches to the functional component.

Regarding claim 31, Koike et al teaches that the probe needle (i.e., functional component) is used to remove sample from the container (column 5, lines 29-52).

Regarding claims 32 and 33, Koike et al teaches that the apparatus comprises a heating block capable of heating the contents of the chamber of the apparatus (column 3, lines 1-4).

Regarding claim 34, Koike et al teaches an ultrasonic oscillator, i.e., physical processor, capable of sonicating the contents of the container of the apparatus (column 8, lines 23-26).

Regarding claim 35, Koike et al teaches introducing the sample into the container in the apparatus (Fig. 13A # S10, column 10, lines 62-65).

Claim 36 recites following structural components a platform comprising: (i) a chamber, (ii) one or more additional chambers comprising pre-dispensed nucleic acid amplification reaction processing reagents and being sealed, (iii) a hole and (iv) a functional component. Koike et al teaches structural components (i) to (iv) except for the

pre-dispensed reagent. Jang teaches chambers comprising pre-dispensed reagent as discussed below.

Regarding structural component (i), Koike et al teaches a turntable 15, i.e., a platform (Fig. 2, column 4, and line 35) comprising a sample container 18 (i.e., chamber) suitable for receiving a sample (Fig. 2, column 4, lines 45-49).

Regarding structural component (ii), Koike et al teaches a container 19 (i.e., additional chamber) and further teaches that the chamber is a sealed chamber (column 7, line 8). Koike et al further teaches that the predetermined amount of liquid is injected into the container on the turntable (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach a sealed chamber comprising pre-dispensed reagent and is sealed.

Regarding structural components 'iii' and 'iv', Koike et al teaches a hole 42a for engagement of fingers 44a and 44b (i.e., a first functional component) to thereby support the fingers (Fig. 6, column 6, lines 25-46).

Regarding claim 37, Koike teaches that the turntable, i.e., platform is circular (Fig. 1).

Regarding claim 38, Koike et al teaches chambers from the reagent stations 66 and 67 are moved to turntable and back to reagent station a sealing mechanism for defining a sealing chamber (Figs. 2 and 13B # S29, column 7, lines 15-20 and column 8, lines 53-58), thus teaching an exchangeable chamber. Koike et al do not teach an exchangeable chamber comprising pre-dispensed reagent.

Claim 40 recites following structural components a platform comprising: (a) a chamber, (b) one or more additional chambers containing predispensed nucleic acid amplification reagents and (c) a first functional component. Koike et al teaches structural components (a) to (c) except for the pre-dispensed reagent. Jang teaches chambers comprising pre-dispensed reagent as discussed below.

It is noted that the platform is defined as "disposable". However none of the structural components of the claimed platform are defined by any special structure that define a disposable property or composition.

Regarding structural component (a), Koike et al teaches a turntable 15, i.e. a platform (Fig. 2, column 4, and line 35) for carrying out a processing operation on a fluid sample further comprising a sample container 18 (i.e., chamber) suitable for receiving a sample (Fig. 2, column 4, lines 45-49).

Regarding structural component (b), Koike et al teaches a container 19 (i.e., additional chamber) and further teaches that the chamber is a sealed chamber (column 7, line 8). Koike et al further teaches that the predetermined amount of liquid is injected into the container on the turntable (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach a sealed chamber comprising pre-dispensed reagent.

Regarding structural component (c), Koike et al teaches a probe needle 26, i.e., a first functional component is on the rack means 11 (Fig. 1, column 5 and lines 53-57) and moved into the containers on the turntable by robot means 13 (column 2, lines 52-53 and column 5, lines 29-59), thereby suggesting probe needle, i.e., first functional component is releasably stored on the turntable. Koike et al also teaches that the

arrangement of sample containers and probe needles on the rack means be moved from platform to the turntable, i.e., platform and vice versa (column 14, lines 26-44) thereby having functional component (i.e., probe needle) releasably stored on the platform.

Regarding claim 41, Koike et al teaches that the turntable 15 (i.e., platform) is adapted to carryout processing operation on a single fluid sample (Fig. 13).

Regarding claims 42 and 43, Koike et al teaches a sealed chamber (column 7, line 8) and further teaches membrane (column 12, line 33). Koike et al do not teach chamber comprises pre-dispensed reagent and chambers are sealed by membrane or metal seal.

Regarding claims 44 and 45, Koike et al teaches probe needle comprises a tip 309 (i.e., second functional component) for inserting into the inner lid 313 of the vessel 311 (Fig. 19, column 13, lines 37-45), thus teaching second functional component interacting with the chamber and comprises a cutter.

Regarding claims 46 and 47, Koike et al teaches magnetic particles and magnet (column 8, lines 17-24). Magnetic particles of Koike et al solid phase material as defined in the instant claims 8 and 9. Koike et al do not teach first functional component comprises separating material for separating a solid phase material from the sample and further comprises a sheath which provides an interface between the separating material and the solid phase material. Koike et al do not teach pre-dispensed reagent comprises a processing reagent bound to a solid phase binding material.

As described above Koike et al do not teach sealed container comprising pre-

dispensed reagents for nucleic acid amplification reaction processing agents. However, sealed container comprising pre-dispensed reagents for nucleic acid amplification reaction processing agents were known in the art at the time of the claimed invention was made as taught by Jang.

Jang teaches an apparatus for isolating nucleic acids comprising a plurality of sealed chamber 15 further comprising pre-dispensed reagents for nucleic acid isolation and amplification (Figs. 1and 5 and paragraphs 0018, 0022, 0026, 0031 and 0037).

Regarding claim 7, Jang teaches silica (paragraph 005, line 3).

Regarding claim 10, Jang teaches an apparatus 300 for isolating nucleic acids comprising a magnetic bar 30 (i.e., first functional component) for attracting solid materials and the complex in the chamber 15 through a bore 24 (Fig. 6, paragraphs 0038-0043). Bore 24 which cover the magnet 30 is reasonably interpreted as sheath.

Regarding claims 15-17, Jang teaches that the chamber comprises pre-filled (i.e., pre-dispensed) reagents and solid materials for processing sample before nucleic acid amplification (paragraphs 0013-0015).

Regarding claims 25, 27, 36, 38, 40 and 42, Jang teaches that the chambers comprising pre-dispensed reagent for use in processing fluid sample are sealed (paragraph 0034).

Regarding claim 43, Jang teaches that the sealing material is aluminum metal seal (paragraph 0034).

Regarding claim 46, Jang teaches an apparatus 300 for isolating nucleic acids comprising a magnetic bar 30 (i.e., first functional component) for separating a solid

phase material from the sample (Jang, claims 28 and 29). Jang also teaches a bore 24 through which magnet bar passes through (Fig. 6, paragraphs 0038-0043). Bore 24 which cover the magnet 30 is reasonably interpreted as sheath.

Jang also teaches pre-dispensed reagents in a sealed chamber are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification (paragraph 0044).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the pre-dispensed reagents in the sealed chamber of Jang in the apparatus of Koike et al with a reasonable expectation of success with the expected benefit of having pre-dispensed reagents in a sealed chamber, which are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification as taught by Jang (paragraph 0044).

10. Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al (USPN 5,305,650 issued Apr. 6, 1994) in view of Lee (WO 98/24548 published Jun. 11, 1998, cited in IDS filed 3/27/2006).

Claim 14 is dependent from claim 1. Teachings of Koike et al regarding claim 1 are described above in section 8.

Regarding claim 14, Koike et al teaches a plurality of container but do not teach that the chamber is coated with electrically conducting polymer. However, coating of the

chamber with an electrically conducting polymer was known in the art at the time of the claimed invention was made as taught by Lee.

Lee teaches a reaction vessel, i.e., a chamber (Fig. 1, # 1) coated with an electrically conducting polymer (Fig. 1, # 3, pg. 11, lines 1-5). Lee also teaches that electrically conducting polymer coated reaction vessels provides an efficient system for rapid heating and cooling of reactions and temperature of the individual vessels is controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the container of Koike et al with chamber coated with an electrically conducting polymer of Lee with a reasonable expectation of success.

An artisan would have been motivated to modify the chamber of Koike et al with a reasonable expectation of success with the expected benefit of having electrically conducting polymer coated reaction vessels providing an efficient system for rapid heating and cooling of reactions and having temperature of the individual vessels controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures as taught by Lee (pg. 5, lines 21-31).

11. Claims 25, 27-29, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al (USPN 5,305,650 issued Apr. 6, 1994) in view of Jang

(USPGPUB 20030082565 filed Fe. 14, 2002) as applied to claims 25 and 36 as above and further in view of Heath et al (USPGPUB 2004/0092731 filed Oct. 20, 1999).

Claims 28 and 29 are dependent from claim 27, which is dependent from claim 25. Claim 38 is dependent from claim 36. Teachings of Koike et al and Jang regarding claims 25, 27 and 36 are described above in section 9.

Regarding claims 28, 29 and 39, Koike et al and Jang do not teach chamber is marked with a bar code and a bar code reader. However, a bar code to mark the chamber and bar code reader were known in the art at the time of the claimed invention was made as taught by Heath et al.

Heath et al teaches an automated nucleic acid isolation apparatus comprising vessel 112 (i.e., chamber) marked with a barcode and further teaches the apparatus comprises bar code reader (paragraph 0080). Heath et al also teaches that the bar code on the chamber identifies the chamber and ensures that there is no contamination or cross-contamination with contents of other chamber or caps (paragraph 0085).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the bar code on the chamber of Heath et al in the apparatus of Koike et al with a reasonable expectation of success with the expected benefit of identifying the chamber and ensuring that there is no contamination or cross-contamination with contents of other chamber or caps as taught by Heath et al (paragraph 0085).

12. Claims 36-38 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squirrell (WO 2002/087762 filed April 18, 2002) in view of Jang (USPGPUB 20030082565 filed Fe. 14, 2002).

Claim 36 recites following structural components a platform comprising: (i) a chamber, (ii) one or more additional chambers comprising pre-dispensed nucleic acid amplification reaction processing reagents, (iii) a hole and (iv) a functional component. Squirrell teaches structural components (i) to (iv) except for the nucleic acid amplification reaction processing reagents, which is taught by Jang et al as discussed below.

Regarding structural component (i), Squirrell teaches a platform for processing a sample prior to nucleic acid amplification reaction, the platform 32 (Fig. 6, pg. 15, lines 3-4) comprising a chamber 39 suitable for receiving a sample (Fig. 6, pg. 9, line 25).

Regarding structural component (ii), Squirrell teaches chambers 13 and 14 containing pre-dispensed reagents for use in the processing and further teaches that chambers are sealed with a metal foil laminate sheet 45 (Fig. 6, pg. 6, lines 8-11, pg. 15, lines 15-20 and 30-31). Squirrell also teaches chambers are for nucleic acid extraction and PCR reaction (pg. 1, lines 11-12 and pg. 4, lines 5-7) but do not teach predispensed nucleic acid amplification reaction processing reagents.

Regarding structural component (iii), Squirrell teaches an open mouth 9a, i.e., hole (Fig. 5 and pg. 11, lines 25-35).

Regarding structural component (iv), Squirrell teaches a cylindrical magnet 30, i.e., functional component in a plunger 4 with a sharp conical tip 4a, i.e., feature and

further teaches that the magnet 30 is releasably supported by the engagement between the functional component and edge of the hole (Fig. 5, pg. 11, lines 13-35).

Regarding claim 37, Squirrell teaches that the housing 1 (i.e., platform) is circular (Fig. 3a).

Regarding claim 38, Squirrell teaches that the support 32 comprises plurality of chambers 34, 36 and 38 with pre-dispersed reagent for use in processing (Fig. 6).

Claim 40 recites following structural components a platform comprising: (a) a chamber, (b) one or more additional chambers comprising pre-dispensed nucleic acid amplification reaction processing reagents and (c) a first functional component. Squirrell teaches structural components (a) to (c) except for the nucleic acid amplification reaction processing reagents, which is taught by Jang et al as discussed below.

Regarding structural component (a), Squirrell teaches disposable unit (pg. 12, line 35) comprising a housing 1, i.e., a platform (Fig. 2, pg. 11, line 13, pg. 12, lines 32-34) comprising a chamber 10 suitable for receiving a sample (Fig. 2, pg. 13, lines 1-5).

Regarding structural component (b), Squirrell teaches a reagent well 11 containing pre-dispensed reagents for the processing operation (Figs. 2, pg. 13, lines 3-6). Squirrell also teaches chambers are for nucleic acid extraction and PCR reaction (pg. 1, lines 11-12 and pg. 4, lines 5-7) but do not teach predispensed nucleic acid amplification reaction processing reagents.

Regarding structural component (c), Squirrell teaches a cylindrical magnet 30, in a plunger 4, i.e., functional component and further teaches that the magnet 30 is releasably stored on the platform such that it can be removed from and replaced onto

the platform (Fig. 5 and pg. 8, lines 30-35). Squirrell also teaches the plunger comprising magnet, i.e., functional component is configured to act as collector for moving the sample (Fig. 6 and pg. 16, lines 1-36 and pg. 17, lines 1-14).

Regarding claim 41, Squirrell teaches that the support unit 32 (i.e., platform) is adapted to carryout processing operation on a single fluid sample (Fig. 6, pg. 15, lines 1-2).

Regarding claims 42 and 43, Squirrell teaches that chambers containing pre-dispensed reagents are sealed with metal seal 45 (Fig. 6, pg. 11, line 19 and pg. 15, lines 30-31).

Regarding claims 44 and 45, Squirrell teaches the plunger 4 comprises a sharp conical tip 4a (i.e., cutter) for puncturing the seal 18 (Fig. 1, pg. 12, lines 5-9).

Regarding claim 46, Squirrell teaches that the plunger 4 comprises a magnet 30 (i.e., separating material) for separating magnetic beads (i.e., solid phase material) from the sample (Fig. 6 and pg. 16, lines 1-8). Squirrell also teaches plunger 4 further comprises a wall (i.e., sheath) surrounding the hole 9a, which provides an interface between the magnet 30 and the magnetic beads (Fig. 5a).

Regarding claim 47, Squirrell teaches that the pre-dispensed reagents comprise pre-dispensed magnetic beads coated with antibodies for capturing target organisms i.e., solid phase binding material (pg. 13, lines 1-2, pg. 16, lines 1-19).

As described above, Squirrell does not teach sealed container comprising pre-dispensed reagents for nucleic acid amplification reaction processing agents. However, sealed container comprising pre-dispensed reagents for nucleic acid amplification

reaction processing agents were known in the art at the time of the claimed invention was made as taught by Jang.

Jang teaches an apparatus for isolating nucleic acids comprising a plurality of sealed chamber 15 further comprising pre-dispensed reagents for nucleic acid isolation and amplification (Figs. 1and 5 and paragraphs 0018, 0022, 0026, 0031 and 0037).

Jang also teaches pre-dispensed reagents in a sealed chamber are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification (paragraph 0044).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the pre-dispensed reagents in the sealed chamber of Jang in the apparatus of Squirrell with a reasonable expectation of success with the expected benefit of having pre-dispensed reagents in a sealed chamber, which are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification as taught by Jang (paragraph 0044).

13. Claims 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squirrell (WO 2002/087762 filed April 18, 2002) in view of Jang (USPGPUB 20030082565 filed Fe. 14, 2002) as applied to claims 36 and 38 as above and further in view of Heath et al (USPGPUB 2004/0092731 filed Oct. 20, 1999).

Claim 38 is dependent from claim 36. Teachings of Squirrell and Jang regarding claims 36 and 38 are described above in section 10.

Regarding claim 39, Squirrell and Jang do not teach chamber is marked with a bar code and a bar code reader. However, a bar code to mark the chamber and bar code reader were known in the art at the time of the claimed invention was made as taught by Heath et al.

Heath et al teaches an automated nucleic acid isolation apparatus comprising vessel 112 (i.e., chamber) marked with a barcode and further teaches the apparatus comprises bar code reader (paragraph 0080). Heath et al also teaches that the bar code on the chamber identifies the chamber and ensures that there is no contamination or cross-contamination with contents of other chamber or caps (paragraph 0085).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the bar code on the chamber of Heath et al in the apparatus of Squirrell with a reasonable expectation of success with the expected benefit of identifying the chamber and ensuring that there is no contamination or cross-contamination with contents of other chamber or caps as taught by Heath et al (paragraph 0085).

14. Claims 1, 5-11, 15-16, 25, 32, 40-44, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiramatsu et al (EP 1219965 published May 29, 2001) in view of Jang (USPGPUB 20030082565 filed Fe. 14, 2002).

Teachings of Hiramatsu et al regarding claims 1, 5, 15 and 25 are described above in section 5.

Regarding claims 6-11 and 32, Hiramatsu et al teaches mixing sample (paragraph 0032) but do not teach the solid phase binding material or attracting material or physical processor

Regarding claim 40, teachings of Hiramatsu et al of structural components (a), (b) and (c) are described above in section 5. Hiramatsu et al do not teach predispensed reagents are nucleic acid reaction processing agents.

It is noted that the platform is defined as "disposable". However none of the structural components of the claimed platform are defined by any special structure that define a disposable property or composition.

Regarding claim 41, Hiramatsu et al teaches that the cartridge container (i.e., platform) is adapted to carryout processing operation on a blood, i.e., single fluid sample (Example 1).

Regarding claims 42 and 43, Hiramatsu et al teaches a sealed chamber containing pre-dispensed reagent (paragraph 0020).

Regarding claim 44, Hiramatsu et al teaches a chip 30 (i.e., second functional component) capable of interacting with the chambers (paragraph 0037).

Regarding claim 47, Hiramatsu et al teaches a sealed chamber containing pre-dispensed reagent (paragraph 0020) for mixing with sample (paragraph 0032) but do not teach processing reagents bound to a solid phase binding material.

As described above Hiramatsu et al do not teach pre-dispensed reagents for

nucleic acid amplification reaction processing agents. However, pre-dispensed reagents for nucleic acid amplification reaction processing agents were known in the art at the time of the claimed invention were made as taught by Jang.

Jang teaches an apparatus for isolating nucleic acids comprising a plurality of sealed chamber 15 further comprising pre-dispensed reagents for nucleic acid isolation and amplification (Figs. 1and 5 and paragraphs 0018, 0022, 0026, 0031 and 0037).

Regarding claims 6-7, Jang teaches solid phase binding material capable of forming complex with analyte is silica (paragraph 005, line 3).

Regarding claims 8-11, 46 and 47, Jang teaches an apparatus 300 for isolating nucleic acids comprising a magnetic bar 30 (i.e., first functional component) for attracting solid materials and the complex in the chamber 15 through a bore 24 (Fig. 6, paragraphs 0038-0043). Bore 24 which cover the magnet 30 is reasonably interpreted as sheath.

Regarding claims 15-16, 42 and 43, Jang teaches that the chamber comprises pre-filled (i.e., pre-dispensed) reagents and solid materials for processing sample before nucleic acid amplification (paragraphs 0013-0015).

Regarding claims 25, 32, 40, Jang teaches that the chambers comprising pre-dispensed reagent for use in processing fluid sample are sealed (paragraph 0034).

Regarding claim 43, Jang teaches that the sealing material is aluminum metal seal (paragraph 0034).

Jang also teaches pre-dispensed reagents in a sealed chamber are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is

not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification (paragraph 0044).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the pre-dispensed reagents in the sealed chamber of Jang in the apparatus of Hiramatsu et al with a reasonable expectation of success with the expected benefit of having pre-dispensed reagents in a sealed chamber, which are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification as taught by Jang (paragraph 0044).

15. Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiramatsu et al (EP 1219965 published May 29, 2001) in view of Lee (WO 98/24548 published Jun. 11, 1998, cited in IDS filed 3/27/2006).

Teachings of Hiramatsu et al regarding claim 1 are described above in section 5.

Regarding claim 14, Hiramatsu et al teaches a plurality of wells, i.e., chambers (Fig. 1) but do not teach that the chamber is coated with electrically conducting polymer. However, coating of the chamber with an electrically conducting polymer was known in the art at the time of the claimed invention was made as taught by Lee.

Lee teaches a reaction vessel, i.e., a chamber (Fig. 1, # 1) coated with an electrically conducting polymer (Fig. 1, # 3, pg. 11, lines 1-5). Lee also teaches that electrically conducting polymer coated reaction vessels provides an efficient system for rapid heating and cooling of reactions and temperature of the individual vessels is

controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the container of Hiramatsu et al with chamber coated with an electrically conducting polymer of Lee with a reasonable expectation of success.

An artisan would have been motivated to modify the chamber of Koike et al with a reasonable expectation of success with the expected benefit of having electrically conducting polymer coated reaction vessels providing an efficient system for rapid heating and cooling of reactions and having temperature of the individual vessels controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures as taught by Lee (pg. 5, lines 21-31).

Response to remarks from Applicants

Claim rejections under 35 U.S.C. § 102(b)

16. Applicant's arguments filed on November 25, 2009 with respect to claims 1-6, 8, 9, 11-13 as being anticipated by Koike et al have been fully considered (Remarks, pg. 8). These arguments are not persuasive for the following reasons.

Applicants assert that probe needle housed separately from the rotatable platform and further argue that it would not be possible to house the probe needle on a rotating platform without causing entanglement (Remarks, pg. 8, paragraph 4).

Applicant's assertion that probe needle is housed separately from the platform is acknowledged. However, as described above in section 6, Koike et al teaches that the arrangement of sample containers and probe needles on the rack means be moved from platform to the turntable, i.e., platform and vice versa (column 14, lines 26-44) thereby having functional component (i.e., probe needle) releasably stored on the platform. Furthermore, Applicant's arguments regarding probe needle is attached to micro-syringe pump is not persuasive because Koike et al teaches probe needles are housed separately on the rack means and not coupled to syringe pump (Figs. 1 and 13, step S13, column 11, lines 1- 4). For these reasons arguments are not persuasive.

Applicant's arguments with respect to claims 36-38 as being anticipated by Clarke et al have been fully considered (Remarks, pg. 9, paragraphs 3 and 4). These arguments are moot in view of claim amendments and withdrawn rejections and new grounds of rejection as set forth in this office action necessitated by claim amendments.

Applicant's arguments with respect to claims 36-38 and 40-47 as being anticipated by Squirrell have been fully considered (Remarks, pg. 9, paragraph 5). These arguments are moot in view of claim amendments and withdrawn rejections and new grounds of rejection as set forth in this office action necessitated by claim amendments. Applicants arguments as it pertains to the teachings of Squirrell used in this office action are directed Squirrell does not teach predispensed nucleic acid amplification reaction processing reagents (Remarks, pg. 9, paragraph 5). This argument is not persuasive because as described above in section 10, nucleic acid processing and amplification reaction processing reagents are taught by Jang for

avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification.

Claim rejections under 35 U.S.C. § 103(a)

17. Applicant's arguments filed November 25, 2009 with respect to claims 1, 5-7, 8, 10, 13, 15-17, 25-27, 30-38 and 40-47 as being unpatentable over Koike et al and Jang et al have been fully considered (Remarks, pg. 10). Applicants arguments are directed to Jang not curing the deficiency of Koike and are not persuasive because as described above, Koike teaches probe needle, i.e., functional component is releasably stored on the platform and teachings of Jang et al are relied on nucleic acid processing and amplification reaction reagents.

Applicant's arguments with respect to claims 1 and 14 as being unpatentable over Koike et al and Lee have been fully considered (Remarks, pg. 10). Applicant's arguments are directed to Jang not curing the deficiency of Koike and are not persuasive because as described above, Koike teaches probe needle, i.e., functional component is releasably stored on the platform and teachings of Lee are relied on chamber coated with electrically conducting polymer.

Applicant's arguments with respect to claims 25, 27-29, 36 and 39 as being unpatentable over Koike et al, Jang et al and Heath have been fully considered (Remarks, pg. 11). Applicant's arguments are directed to Jang not curing the deficiency of Koike and are not persuasive because as described above, Koike teaches probe

needle, i.e., functional component is releasably stored on the platform and teachings of Lee are relied on chamber having a barcode.

Conclusion

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634